



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,088	10/24/2003	Mark G. Fontenot	4012.13	8477

7590 04/30/2008
STEVEN M. COLBY, PH.D.
PETERS VERNY, LLP
SUITE 230
425 SHERMAN AVENUE
PALO ALTO, CA 94306

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
----------	--------------

1612

MAIL DATE	DELIVERY MODE
-----------	---------------

04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/693,088

Applicant(s)

FONTENOT, MARK G.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 21, 22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 21, 22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date 09 Apr 2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Amendment filed February 11, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 101- Non-Statutory Subject Matter (New Rejection)

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite a composition that is not isolatable making it non-statutory subject matter. Stated alternatively, since the claimed "composition" will constantly change depending on conditions in the oral cavity, e.g. washing by saliva, there is no one "composition" to be claimed which can serve as a statutory representative of same.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1612

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1) The claim recites the limitation "configured to enhance said performance". There appears to be a lack of support for this limitation in the instant specification. Therefore the limitation is New Matter.

2) The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Claim 25 also lacks written description insofar as the instant specification does not set forth how the composition is "configured to enhance said performance". As stated above the phrase does not appear to be supported by the specification therefore there are no examples for one of skill in the art to determine how the performance is improved. For example, it cannot be determined if the concentrations of each

component were adjusted to enhance performance or if a component was added to enhance performance.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

Claims 1-6 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 1-6 are indefinite insofar as they recite a composition that is not stable and therefore is not isolatable. It cannot be determined if the claims are reciting a composition when it is only on the surface of the tooth or in the oral cavity. Furthermore Applicant does not specify other components such as the components in the pellicle as argued, which Applicant asserts are a part of the claimed compositions. As the claims stand, they encompass compositions comprising pellicle matter as well as a compositions that not comprising pellicle matter because the instant claims recite any tooth surface. Therefore it cannot be reasonably concluded what the compositions of the instant claims encompass.

2) Claim 25 is indefinite insofar as it uses the phrase "configured to enhance said performance" but does not disclose what the configuration encompasses and how it enhances performance.

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

Claims 21-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Ambuter et al. (US 5,997,764). This rejection is maintained and further applied to claim 25.

Applicant's Arguments

Applicant argues Ambuter et al. does not teach a composition comprising a flavoring agent in combination with hypochlorites and also does not teach a flavoring agent in the specific amount of between about 0.001 and 5% by weight. The reference never discloses hypochlorite and flavors together in any of the disclosed embodiments. The reference also implies that hypochlorite bleaches are too harsh and therefore not suitable for oral care application and oral products are not mentioned in the reference. Applicant also asserts that flavors are included in a laundry list of other optional additives. These arguments are not persuasive.

Examiner's Response

Ambuter et al. disclose a formula comprising DI water, Carbopol 672, a Rheology stabilizer which includes cinnamic acid (a flavoring¹), sodium hydroxide and sodium hypochlorite. This formulation encompasses the instant claims. The rheology modifier may also be methyl salicylate encompassing claim 22.

¹ Sprecker et al. (US 4,224,346) col. 10, lines 46-50.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

In order to ensure completeness of prosecution, the following art rejections are maintained. Although the instant claims are rejected under USC 101 as being drawn to non-statutory subject matter, rejections over prior art merely requires that the composition exist or is reasonably expected to exist, not that it be statutory, therefore the following rejections are maintained.

1) Claims 1-6, 14, 15 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Howes (US 2002/0098246). The rejection is maintained and withdrawn in regards to claims 14, 15 and 17.

Applicant's Arguments

Applicant argues the claims have been amended to recite that the composition is made by applying the primer comprising hypochlorite to the teeth followed by the peroxide composition. Applicant asserts the composition formed in the instant claims is a product of the reaction of the pellicle with the primer followed by the further reaction of that product with the tooth whitening composition. This composition is different from a composition produced from the primer and the tooth whitening compositions applied simultaneously or the tooth whitening applied before the primer. Howes only teaches simultaneous application and sequential application with the peroxide preceding the hypochlorite. Applicant also asserts unexpected results and discusses Tables 1 and 3.

Examiner's Response

The claims recite the composition is made by applying the primer to a tooth surface followed by applying a whitening composition. Nowhere in the independent or dependent claims does it recite a tooth surface where pellicle matter is on the teeth. The compositions encompass those surfaces comprising pellicle matter and surfaces that do not. Therefore the order of application encompasses that of the reference because it forms substantially the same composition. Furthermore the compositions may be administered sequentially and therefore also encompass the instant claims. Selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. See MPEP 2144.04, IV C. Although Applicant asserts unexpected results, the comparison is not with the closest prior art or similar systems comprising hypochlorite and peroxide nor do the results disclose how the order of application affects the whitening effect. Table 3 also shows that the whitening occurred slowly, moderately and quickly in different patients and therefore it cannot be concluded if these are unexpected results because there is no comparison with other systems comprising hypochlorite or reversing the order of Application. Furthermore the compositions used in the table are not commensurate in scope with the instant claims for instance certain concentrations are used for each compositions whereas the claims do not recite any particular concentration. Therefore the rejection is maintained.

2) Claims 1-4, 6, 14-18 and 23-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over van den Bosch (US 6,017,515). The rejection is maintained in regards to claims 1-4 and 6. Claims 14-18, 23 and 24 are cancelled.

Applicant's Arguments

Applicant argues as above that the claims are amended to recite the primer solution is applied to the surface of the teeth before the whitening composition. Applicant asserts due to the sequence of application, the primer reacts with the pellicle of the teeth forming a product where this product forms another composition when the whitening composition is added. The compositions of the reference are applied simultaneously. Although the reference teaches a method of applying hypochlorite first, an etchant was used to clean the teeth prior to application of the hypochlorite and therefore removes the pellicle from the teeth. Therefore the composition of the reference is not the same as that of the instant claims. Applicant also asserts that the time of for bleaching action to occur in the reference is longer than that of the instant claims. These arguments are not persuasive.

Examiner's Response

See Examiner's response above. There is no mention in the claims that the compositions comprise pellicle from the teeth. The recitation of tooth surface encompasses teeth with and with pellicle matter. In regards to the unexpected results,

Art Unit: 1612

Applicant compares the result with that of compositions comprising no hypochlorite and not with those comprising hypochlorite. Additionally it cannot be concluded that the compositions of the instant claims have unexpected results over the prior art because the data reported was not run under the same conditions as that of the reference. Applicant also does not appear to report the results of applying the peroxide before the hypochlorite. Lastly the compositions used for experimentation are not commensurate in scope with the instant claims. Therefore the rejection is maintained.

3) Claims 1-6, 14-17 and 21-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Jung (US 2006/0060819). The rejection is maintained in regards to claims 1-6, 21 and 22 and further applied to claim 25. Claims 14-17, 23 and 24 are cancelled.

Applicant's Arguments

Applicant argues Jung teaches applying the compositions simultaneously. See Applicant's arguments above. Applicant also argues that the reference does not disclose the pH and it would only be obvious to optimize the pH if the general conditions of a claim are actually disclosed in the prior art. Applicant supports this position with *In re Antonie*. Applicant also compares the instant case with an example comparing a submarine with an airplane. Applicant asserts, although prior art of a submarine may read on a commercial airplane, the commercial airliner would not satisfy the general conditions of the submarine. Therefore it is not sufficient to simply argue that because the Examiner takes the position that Jung anticipates every limitation of claims 21 other

than the particular pH range therefore Jung satisfies the general conditions of claim 21 and it would be obvious to optimize the teaching of Jung within particular range of a pH greater than about 8.5 to about 13. Therefore it would be obvious to optimize the commercial airliner to operate at a depth of between 50 and 500 meters because it otherwise anticipates the submarine claim. The Examiner has not shown that the dentifrice paste of Jung discloses the general conditions of the claimed primer solution, and the Applicant argues that the dentifrice paste clearly does not disclose the general conditions of the claimed primer solution. Applicant further asserts the differences between the compositions of the instant claims and the reference (see page 17 of the arguments). Applicant also contends that the pH requirements for a dentifrice will be different than those for the claimed primer and not necessarily in the range of greater than about 8.5 to about 13. Further, the mere presence of hypochlorite as a component of the dentifrice does not dictate what an appropriate pH will be. Put another way, if a group of product designers were trying to optimize the pH of a dentifrice, the fact that hypochlorite was a component would not drive the designers to particularly optimize the pH within the range of greater than about 8.5 to about 13. The Applicant believes that considerations such as avoiding chemical burns in the mouth would be one factor that would tend to weigh against optimizing the pH of a dentifrice in the range of greater than about 8.5 to about 13. Applicant further asserts unexpected results and supports this position with *In re Waymouth*. Applicant also asserts the Examiner appears to be viewing the scope of the claims incorrectly (see page 18 of arguments). Applicant further asserts it is clear that the pH will not necessarily be in the claimed range just

because hypochlorite is a further constituent. The simultaneous application of hypochlorite and peroxide would not result in the claimed composition of claim 1. These arguments are not persuasive.

Examiner's Response

See Examiner's response above. In regards to the airplane and the submarine, one travels through the air and one travels under water. In the instant case the compositions of the instant claims and the compositions of the reference are used to clean the teeth. The pH of the compositions is a result effect component and therefore it would be obvious to optimize the pH to obtain optimal results. Furthermore Applicant uses open language therefor components such as those disclosed by Jung that are in the compositions of the reference are also encompassed by the instant claims. In regards to one of skill in the art optimizing the pH of the hypochlorite component, one of skill in the art would use the pH as recited by the instant claims based on the knowledge disclosed by prior art. Peroxide has an acidic pH and is activated to whiten teeth by raising its pH. This is done by using a basic component². Therefore it would have been obvious to optimize the pH of the hypochlorite so that when the two components are mixed the pH of the peroxide is raised to a level where it can whiten the teeth. In regards to the Examiner viewing the scope of the claims incorrectly, the Examiner is aware that other components may be in the compositions. The Examiner points out that the other components may also only be water. Therefore the Examiner is not incorrectly

² Orłowski et al. (US 6,365,134) col. 4, lines 33-60.

Art Unit: 1612

viewing the scope of the claims the Examiner is interpreting the claims based on their broadest interpretation. Furthermore the statement Applicant is referring to in the arguments is not made in reference to Jung or claim 21 and therefore is not relevant to claim 21 as argued. The Examiner is not asserting that the pH of the hypochlorite solution will be in a certain range because hypochlorite is present in the instant rejection. The Examiner's position is that one of skill in the art would have adjusted the pH to optimize whitening effect of the peroxide when the hypochlorite component is mixed with the peroxide component. In regards to unexpected results see Examiner's response above.

Claims 1-6, 21, 22 and 25 are rejected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1612

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612